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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,177	12/21/2001	Craig P. Hunter	42697.122US2	7824

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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 07/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/038,177

Applicant(s)
Craig et al.

Examiner
Joyce Tung

Art Unit
1637



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 14, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-58 and 66-79 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-58 and 66-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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DETAILED ACTION

1. The amendment filed 5/14/2003 has been entered. Following the entry of the amendment, claims 53-58 and 66-79 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 53-56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nycz et al. (Analytical Biochemistry, 1998, Vol. 259, pg. 226-234).

Nycz et al. disclose quantitative reverse transcription strand displacement amplification comprising AMV reverse transcriptase and single-strand binding protein from gene 32 of T4 bacteriophage to enhance strand displacement replication (See pg. 226, the Abstract). The

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amount of T4gp32 single strand binding protein is 4.8 μ g in a final volume of 50 μ l (See pg. 228 column 1, the last paragraph to column 2 first paragraph). The temperature of the reaction is 45C⁰-53C⁰ (See pg. 231, column 2, second paragraph).

Nycz et al. do not disclose the completed reverse transcription of mRNA molecules which are greater than 600 nucleotides in length, the concentration of the single- strand binding protein recited as 0.0061mM or 0.015 in claims 54 and 55, and the temperature of the reaction carried out is not more than 42C⁰.

However, one of ordinary skill in the art at the time of the instant invention would have been motivated to combine of reverse transcriptase and single-stranded binding protein because with the inclusion of the single-strand binding protein, the amplification efficiency increases (See pg. 226, column 1, the Abstract). Moreover, one of ordinary skill would have also varied the reaction condition by optimizing the concentration of the single-strand binding protein and the temperature of the reaction in order to optimize the reaction condition to maximize the amount of transcription product as it was routine procedure to optimize reagent condition in assays. It would have been prima facie obvious to synthesize cDNA molecules with combining an mRNA molecule longer than 600 nucleotides in length with a reverse transcriptase and a single -strand binding protein at a concentration sufficient to promote completed reverse transcription of mRNA molecules greater than 600 nucleotides in length.

The response filed 5/14/2003 argues that Nycz et al. do not provide teachings or explanation of the basis for the improvement in “amplification efficiency” and Nycz et al.

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suggest that the single-strand binding protein ^{is used} improves ^a the post reverse transcription step of amplification. However, Nycz et al. disclose that quantitation of RNA could be achieved during the linear amplification phase of the reaction over a 10-min time frame (See 232, column 1, third paragraph). This teaching suggests that the linear amplification phase of the reaction is fast. Thus, Nycz et al. do disclose the improvement in “amplification efficiency”. Nycz et al. also indicate that T4gp32 single-strand binding protein, and reverse transcriptase were added in the reaction at the same time (See pg. 228, column last paragraph). Therefore, it is difficult to say whether or not the single-strand binding protein improves the post reverse transcription step of amplification as the response argued.

The response filed 5/14/2003 also argues that Nycz et al. do not teach the single-strand binding protein in a reverse transcription process would serve the purpose of promoting the completed reverse transcription of mRNA. Nevertheless, the phrase “completed reverse transcription of mRNA” can not determine whether or not full length of mRNA is amplified. Thus, the teachings of Nycz et al. read broadly on the limitations of the claims.

The response filed 5/14/2003 further argues that Nycz et al. do not disclose synthesizing completed cDNA's from mRNA molecules that are greater than 600 nucleotides long. Nycz et al. disclose that a portion of the HIVgag-1 gene sequence is used in amplification (See pg. 226, column 2, last paragraph) and a portion of the HIV gag-1 gene was cloned and identical to HIV MN and corresponds to positions 1222-1839. The mRNA is more than 600 nucleotides in length.

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The response filed 5/14/2003 further argues that the claimed invention is not directed to amplification, it is directed to a method for synthesizing cDNA molecules. However, the claims do not require any specific steps for synthesizing cDNA, while the claims require “reverse transcriptase and a single-strand binding protein at a concentration sufficient to promote completed reverse transcription of mRNA molecules greater than 600 nucleotide in length” Therefore, it is unclear what is the difference between “amplification” and “synthesizing”. The teachings of Nycz et al. read broadly on the limitations of claims. Thus the rejection is maintained.

The newly added claims 66-79 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Nycz et al. (Analytical Biochemistry, 1998, Vol. 259, pg. 226-234).

Based upon the teachings of Nycz et al. and the discussion of the argument in the response above, the teachings of Nycz et al. still read broadly on the limitations of the newly added claims 66-79 (See pg. 227, fig. 1).

4. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nycz et al. (Analytical Biochemistry, 1998, Vol. 259, pg. 226-234) as applied to claims 53-56 and 58 above, and further in view of Cleuziat et al. (5,849,547).

The teachings of Nycz et al. are set forth in section 3 above.

Nycz et al. do not disclose the single strand binding protein comprising the single strand binding protein of *E.coli*.

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Cleuziat et al. disclose a method of amplifying a target nucleic acid sequence (RNA and/or DNA) by transcription reaction using displacement (See column 5, lines 66-67 and column 6, lines 1-2). The reaction comprises reverse transcriptase and single-strand binding protein from *E.coli* (See column 12, lines 40-60).

One of ordinary skill in the art would have been motivated to modify the method of Nycz et al. by using the single strand binding protein from *E.coli* as taught by Cleuziat et al. because the single-strand binding protein could be used in promoting the strand displacement (See column 12, lines 54-57). It would have been prima facie obvious to carry out the method as claimed.

The response filed 5/14/2003 argues that the reference of Cleuziat et al. do not provide any motivation to combine reverse transcriptase and single strand binding protein to synthesize full-length cDNA from mRNA. Nevertheless, the claims do not require synthesizing full-length cDNA from RNA. The teachings of Cleuziat et al. read broadly on the limitations of claims. Thus the rejection is maintained.

Summary

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal

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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J.T.
July 22, 2003

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER
7/27/03